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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,684	10/25/2001	David P. Katz	AMBIINC.006A	3175

20995 7590 11/28/2003

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EXAMINER	
PATTEN, PATRICIA A	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 11/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	10/001,684	KATZ, DAVID P.	
	Examiner	Art Unit	
	Patricia A Patten	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

RCE Practice

A request for continued examination under 37 CFR § 1.114, including the fee set forth in 37 CFR § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR § 1.114, and the fee set forth in 37 CFR § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR § 1.114. Applicant's submission filed on 11/10/2003 as well as the Amendment filed After Final rejection (9/8/2003) has been entered.

Claims 1-25 are pending in the application.

It is noted that Applicants have provided a summary of the Interview conducted between the Attorneys and the Examiner as well as Brenda Brumback on 10/25/03. It is noted that Applicants have not received the Interview summary which was documented by the Examiner. A response to this Interview summary, attached hereto is necessary in response to this Office Action. It is noted that the Applicants stated, "Narrowly, the PTO stated its opinion that the transitional phrase 'consisting essentially of' excludes all active ingredients that have a deleterious effect on the intended use of the claimed composition but does not exclude complimentary or facilitating ingredients". However,

the Examiner did not state this. This phrase was analyzed in context to the scope of the Instant specification, and the content of the prior art for the purpose of examining a single set of claims and did not broadly make any assertions with regard to every instance of the recitation of 'consisting essentially of'.

Election/Restrictions

Applicant's arguments pertaining to the withdraw of claims 21-25 in the Final Office Action were fully considered. Applicant's arguments are persuasive. The subject matter of claims 21-25 fall within the scope of original claim 1 and will thereby be examined on the merits along with claims 1-20.

Claims 1-25 were examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, claim 16 recites 'purified chromium-containing compound'. It is not found in the original disclosure where this idea (purified) was contemplated, thereby rendering this term New Matter. Because claims 17-20 depend upon claim 16, all of these claims necessarily contain every limitation of claim 16 and therefore subsequently contain this New Matter. Applicant is asked to either delete this term from claim 16 or to clearly point out where this term is supported in the Instant disclosure.

It is noted that the rejection under 35 USC 112 Second paragraph has been removed. Arguments were persuasive, the term 'consisting essentially of' does have a defined meaning, and the claims clearly state a 'basic and novel characteristic' being treatment of PCOS. It is noted that Applicants arguments pertaining to this rejection include arguments for the inclusion of chelating agents "the purpose for the chelating agents is to enhance the absorption of chromium". Here, the Applicant is asserting that the addition of a chelating agent, which beneficially acts on the chromium, is within the

metes and bounds of 'consisting essentially of'. (it is noted that the chelating agent is a separate entity from the chromium complex).

Claim Rejections - 35 USC § 103

Claims 1-20 remain rejected, and claims 21-25 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over de la Harpe et al. (US 5,980,905) in view of Ostlund et al. (US 5,550,166).

Claims 20-24 newly recite wherein the chromium complex is 'purified'. Claims 21-25 are drawn to wherein the chromium complexes are synthetic.

de la Harpe et al. specifically taught that as a preferred embodiment, the chromium complexes; chromium tripicolinate and chromic polynicotinate were synthetic (col.4, lines 13-18). Thus, one of ordinary skill in the art would have been motivated to have substituted naturally occurring chromium complexes with synthetic chromium complexes such as chromium tripicolinate because there would have been a reasonable expectation that the synthetic complexes would have been a functional equivalent to the naturally occurring compounds, especially since they perform the same functions (col.4, lines 18-24).

It was routine in the art to pharmaceutically administer purified compounds to patients in order to decrease negative effects of residual contaminants (i.e., allergic reactions). One of ordinary skill in the art would have been motivated to have administered a purified chromium complex in order to ensure the benefits of the chromium complex without any unwanted reactions due to contaminants.

Applicant's arguments were fully considered, but not found persuasive.

Applicant's principal argument resides in the contention that de la Harpe et al. did not teach wherein the chromium complexes alleviated insulin resistance (IR). Applicants state that IR "is defined as the diminished ability of cells to respond to the action of insulin in transporting glucose (sugar) from the blood stream into muscle and other tissues" (p.10-arguments). It is noted that Applicants did not provide any of the cited references, and therefore, the Examiner has considered Applicant's comments, has not considered these cited references in their entirety. Applicants further argue that "...while IR may be a sign of a pre-diabetic condition and that a person diagnosed with diabetes may display symptoms of IR, the two conditions are not one and the same and certainly do not need to co-exist in any one patient (p.11-Arguments). The Examiner agrees. Manifestation of type 2 diabetes is a result of either insulin resistance or a lack of the pancreas to produce sufficient insulin. Thus, certain drugs administered for type 2 diabetes stimulate the beta cells to produce insulin. However, that is not the case of de la Harpe, which makes it clear, albeit implicitly, that chromium functions to decrease

insulin resistance for the following reasons. de la Harpe et al. disclosed that it was well known that chromium depletion led to disturbed glucose metabolism (col.1, lines 25-32). Additionally, as reiterated by Applicants, de la Harpe et al. stated that 'Chromium functions as a cofactor for insulin. It binds to the insulin receptor and potentiates many, and perhaps all of its functions". de la Harpe et al. did not simply propose this function; it was well known in the art as readily disclosed by Boyle et al. (as cited by de la Harpe et al. col.1, line 56). It is well known that insulin stimulates fat and muscle cells to take up glucose. Since chromium complexes show an improvement in glucose tolerance, the ability of the body to transport glucose, as evidenced by de la Harpe et al., and do not increase insulin production as some diabetes-type 2 drugs, the insulin must have been potentiated, as clearly disclosed by de la Harpe et al.. In order for glucose metabolism to be corrected, insulin resistance must have been corrected to some degree in order to result in the positive outcome which is shown as improved glucose tolerance in diabetes-type-2 (i.e., col.2, lines 25-37). The ordinary artisan would therefore have had a reasonable expectation that chromium complexes corrected insulin resistance, and in turn would have expected that chromium complexes would have been advantageous in treating diseases, which were characterized, or at least included, insulin resistance such as polycystic ovary syndrome.

Applicants argue that:

> "The Instant specification states that women with PCOS are at increased risk for developing impaired glucose tolerance (IGT)...and type II diabetes...while some women diagnosed with PCOS will go on to develop IGT and type II diabetes, others will not. The prior art discloses the utility of chromium supplementation to treat the symptoms of diabetes. However, nothing in the prior art or the specification suggests that diabetes is causing PCOS or that there is even a causal relationship between the two conditions" (Arguments bridging pages 12-13).

However, as indicated in previous Office Actions, the Instant specification, read as a whole, does not specify the use of chromium complexes for any other use besides improved glucose and lipid profiles. No other nexus between chromium activity and PCOS has been established within the Instant specification, nor have any unexpected results been exemplified within the Instant disclosure. The Instant specification further recites: " "The primary basis of the present invention is the novel and unexpected discovery that chromium complexes lower blood glucose levels, thereby ameliorating some of the symptoms associated with PCOS" (p.10, Instant specification). It is made clear from the prior art that it was *well known at the time the Invention was made* that chromium complexes normalized/lowered blood glucose levels. Applicants recite 'some of the symptoms' however, the Examiner can only conclude that glucose and lipid levels showed some improvement as seen in the Example on p. 16 of the Instant specification. Applicants have not clearly shown or described any other symptoms of PCOS which are

alleviated via the administration of chromium complexes and have not provided an absolute nexus between glucose tolerance and all symptoms of PCOS.

The rejections therefore remain standing.

No claims are allowed.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A Patten whose telephone number is (703) 308-1189. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (703) 306-3220. The fax phone

number for the organization where this application or proceeding is assigned is (703) 872-3906.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Patricia A Patten
Examiner
Art Unit 1654

11/19/03

PATRICIA PATTEN
PATENT EXAMINER